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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Erickson et al.
Serial No.:	10/627,233
Filed:	July 25, 2003
For:	BENDABLE NEEDLE WITH REMOVABLE STYLET
Group No.:	3738
Confirmation No.:	2444
Examiner:	Christopher D. Prone

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents
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APPEAL BRIEF

Appellant has appealed to the Board of Patent Appeals and Interferences from the decision of the Examiner dated December 12, 2005, finally rejecting Claims 1-6 and 29-31. Appellant filed a Notice of Appeal on March 10, 2006. Appellant respectfully submits this brief on appeal with the appropriate statutory fee.

REAL PARTY IN INTEREST

The real party in interest is Advanced Neuromodulation Systems, Inc.

RELATED APPEALS AND INTERFERENCES

There are no known appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board's decision in this pending appeal.

STATUS OF CLAIMS

Claims 1-6 and 29-31 have been rejected pursuant to a final Office Action dated December 12, 2005. Claims 1-6 and 29-31 are the claims being appealed.

Claims 8-21 and 24-28 have been cancelled. Claims 7, 22, and 23 are withdrawn from consideration due to a restriction requirement.

A copy of the claims is provided in an accompanying appendix.

STATUS OF AMENDMENTS

No amendments were submitted after issuance of the final Office Action dated December 12, 2005.

SUMMARY OF CLAIMED SUBJECT MATTER

The present application is generally related to a needle that can be used to insert medical devices within the body of a patient such as a neurostimulation lead. The needle is adapted to receive a stylet to provide mechanical rigidity to the needle during insertion and traversal of the needle through tissue. The stylet prevents encroachment of tissue into the needle when the needle is

inserted into the patient. The needle is further bendable to allow the needle to be navigated through the patient to avoid damaging certain tissues and to avoid tissues that would block entry of the needle to the desired location (e.g., within the spinal foramen of the patient). *See, e.g.,* application, paragraphs [0004] and [0030]. The needle is adapted to allow the surgeon to bend the needle (with the stylet inserted therein) without trapping the stylet within the needle as would typically occur in conventional needles. *See* application, paragraph [0006]. That is, when conventional steel or metal stylets are used in conventional needles, the bending of the needle frequently causes the metal stylet to become “stuck” within the needle making removal of the stylet (to allow insertion of the neuromodulation lead through the needle) difficult or impossible. *See* paragraph [0044].

In one embodiment, a bendable needle system comprises: a bendable tubular needle (see FIGS. 1A and 1B of the application) having at least one sharp cutting end (see element 14 in FIG. 1); and a removable stylet (see the stylet depicted in FIG. 2) inserted in a hollow interior (see element 12 in FIG. 1A) of the bendable tubular needle. *See* paragraph [0032]. The removable stylet further comprises a flexible stylet body (see coil 22 in FIG 2 and paragraph [0036]) that allows the stylet to bend within the bendable tubular needle; and a tip that aligns flush to the sharp cutting end of the bendable tubular needle (see tip 18 in FIG. 2 and paragraph [0040]); wherein the bendable tubular needle is bendable by manual manipulation when the removable stylet is inserted in the bendable tubular needle and the removable stylet remains removable from the bendable tubular needle after the bendable tubular needle is bent. Paragraphs [0036], [0038], [0044], and [0045].

In another embodiment, a bendable needle system, comprises (i) a bendable tubular needle having a sharp cutting end (element 14 in FIG. 1) at a distal end and a hollow fitting structure (see fitting 20 in FIG. 1) at a proximal end; (ii) a removable stylet, of variable length (see coil 22 in FIG. 2), inserted in a hollow interior of the bendable tubular needle, wherein the removable stylet further comprises (a) a fitting structure (see fitting 20 in FIG. 2 and paragraph [0036]) adapted to mate with the hollow fitting structure of the bendable tubular needle; (b) a flexible stylet body that allows the stylet to bend within the bendable tubular needle (paragraph [0045]), wherein the flexible stylet body aids in maintaining patency of the bendable tubular needle when the bendable tubular needle is bent (paragraph [0037]); and (c) a tip, wherein the fitting structure, when mated with the hollow fitting of the bendable tubular needle, compresses the flexible stylet body to maintain the tip in an alignment against the sharp cutting to form a flush surface at the distal end of the bendable tubular needle (see coil 22 in FIG 2, FIGS. 7A and 7B and paragraphs [0036], [0038], [0045] and [0046]); wherein the bendable tubular needle is bendable by manual manipulation when the removable stylet is inserted in the bendable tubular needle and the removable stylet remains removable from the bendable tubular needle after the bendable tubular needle is bent (paragraphs [0045] and [0046]).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-6 and 29-31 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,608,539 to Miller (hereinafter referred to as "Miller").

ARGUMENT

A. CLAIMS ON APPEAL

Claims 1-6 and 29-31 are rejected under 35 U.S.C. § 102(b) as being anticipated by Miller.

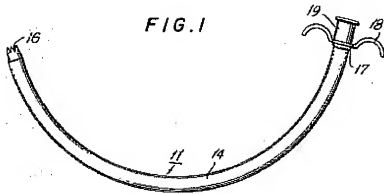
Applicant respectfully submits that Miller does not anticipate claims 1-6 and 29-31 and requests reversal of the rejection.

B. REQUIREMENTS FOR AN ANTICIPATION REJECTION

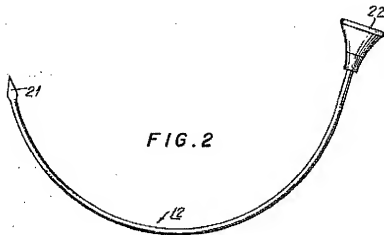
A prior art reference anticipates a claimed invention under 35 U.S.C. § 102 only if every element of the claimed invention is identically shown in that single reference, arranged as they are in the claims. (*MPEP* § 2131; *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (*Fed. Cir.* 1990)). Anticipation is only shown where each and every limitation of the claimed invention is found in a single prior art reference. (*MPEP* § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (*Fed. Cir.* 1985)).

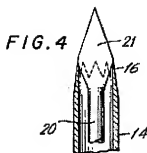
C. THE DISCLOSURE OF MILLER

Miller discloses an instrument for conducting a biopsy of subcutaneous masses. See Abstract of Miller. There are three separate structures disclosed in Miller for conducting the biopsy. The first structure is arcuate cannula 11 having a serrated distal cutting end which is shown in FIG. 1 of Miller and reproduced below.



Miller further discloses stylet 12 (also referred to as a "piercing" member 12) which, in use, is inserted in the bore of cannula 11. Specifically, cannula 11 with stylet 12 placed therein is inserted in the patient to access the mass to be biopsied. Stylet 12 is shown in isolation in FIG. 2 of Miller and the top of cannula 11 with stylet 12 inserted therein is shown in FIG 4 as reproduced herein below. Rod 20 (as shown in FIG. 4) of stylet 12 is specifically disclosed by Miller as being a rod of stainless steel of 2 millimeters in diameter. Col. 2, lines 70-71.





During the biopsy procedure, cannula 11 and stylet 12 are advanced through the skin toward the mass to be biopsied. When the mass is reached, stylet 12 is removed and the cannula 11 is advanced until cannula 11 exits the skin at another location. By continuing to advance cannula 11 without stylet 12 inserted therein, a tissue sample of the mass is obtained. Then ejector member 13 (as shown in FIG. 3 and reproduced below) is advanced through cannula 11 to force the tissue sample out of cannula 11. Ejector member 13 is merely described as a flexible rod or wire such as a Teflon rod. Col. 2, lines 59-63.



D. CLAIM 1 AND DEPENDENT CLAIMS 2-6

Claim 1 recites:

a removable stylet inserted in a hollow interior of the bendable tubular needle,
wherein the removable stylet further comprises:

- a flexible stylet body that allows the stylet to bend within the bendable tubular needle; and
- a tip that aligns flush to the sharp cutting end of the bendable tubular needle;

wherein the bendable tubular needle is bendable by manual manipulation when the removable stylet is inserted in the bendable tubular needle and the removable stylet remains removable from the bendable tubular needle after the bendable tubular needle is bent.

There are only two possible structures in Miller that could be proposed to satisfy the “removable stylet” limitation of claim 1. These structures are stylet 12 of Miller and ejector member 13 of Miller. However, neither of these structures satisfy all of the elements of the recited “removable stylet” of claim 1.

Appellant respectfully submits that the rejection impermissibly mixes, matches, and combines the characteristics of the two different structural elements of Miller. However, the elements shown in an applied reference under 35 U.S.C. § 102 must be arranged exactly as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Appellant notes that claim 1 requires a “removable stylet” which, in turn, comprises “a flexible stylet body” and “a tip that aligns flush to the sharp cutting edge of the bendable tubular needle.” Furthermore, claim 1 recites “wherein the bendable tubular needle is bendable by manual manipulation when the removable stylet is inserted in the bendable tubular needle and the removable stylet remains removable from the bendable tubular needle after the bendable tubular needle is bent.”

Appellant submits that there is no single flexible stylet in Miller that satisfies all of these requirements.

Appellant submits that stylet 12 of Miller does not satisfy these requirements of the removable stylet as recited in claim 1. First, stylet 12 is explicitly described by Miller as being constructed of “stainless steel of 2 millimeters in diameter.” Col. 2, lines 70-72. There is no

evidence or reason to believe that, when stylet 12 is placed within cannula 11 of Miller and cannula 11 is bent, stylet 12 would be removable from cannula 11. Instead, Appellant respectfully submits that, because both cannula 11 and stylet 12 are stainless steel elements, stylet 12 would be retained in cannula 11. *See* paragraphs [0005] and [0006] of the present application. Instead, Appellant submits that stylet 12 would be “stuck” in cannula 11 as described in regard to the discussion of convention needle designs in the present application.

Additionally, Appellant respectfully submits that “ejector member 13” does not satisfy the requirements of the removable stylet of claim 1. Specifically, Miller explicitly states that ejector member 13 is “[a] blunt ended flexible ejector”. Col. 1, lines 70-71 (emphasis added). Thus, ejector member 13 cannot be fairly said to include “a tip that aligns flush to the sharp cutting edge of the bendable tubular needle” as recited by claim 1.

Because there is no structure in Miller that possesses all of the recited elements of the “removable stylet” of claim 1, Miller does not anticipate claim 1. Claims 2-6 depend from claim 1 and are, likewise, not anticipated by Miller.

E. INDEPENDENT CLAIM 29 AND DEPENDENT CLAIMS 30-31

Claim 29 recites:

a bendable tubular needle having a sharp cutting end at a distal end and a hollow fitting structure at a proximal end;
a removable stylet, of variable length, inserted in a hollow interior of the bendable tubular needle, wherein the removable stylet further comprises:
a fitting structure adapted to mate with the hollow fitting structure of the bendable tubular needle;

a flexible stylet body that allows the stylet to bend within the bendable tubular needle, wherein the flexible stylet body aids in maintaining patency of the bendable tubular needle when the bendable tubular needle is bent; and

a tip, wherein the fitting structure, when mated with the hollow fitting of the bendable tubular needle, compresses the flexible stylet body to maintain the tip in an alignment against the sharp cutting end to form a flush surface at the distal end of the bendable tubular needle;

wherein the bendable tubular needle is bendable by manual manipulation when the removable stylet is inserted in the bendable tubular needle and the removable stylet remains removable from the bendable tubular needle after the bendable tubular needle is bent.

For the reasons discussed above in regard to claim 1, Appellant submits that claim 29 is not anticipated by Miller.

Also, there is no disclosure in Miller of a flexible stylet “of variable length.” Miller only discloses stylet 12 and ejector member 13. Stylet 12 is disclosed as including rod 20 of stainless steel which clearly is not “of variable length.” Ejector member 13 is only disclosed as being formed of Teflon rod or a wire having an outside diameter about equal to the inside diameter of the cannula of Miller. Col. 2, lines 59-63. There is no basis in Miller to conclude that the Teflon rod or wire is of “variable length.”

The rejection argues that the stylet of Miller is inherently of “variable length,” because the operator would select the appropriate size for the patient being operated on. Office Action, page 3. This argument is insufficient to support a rejection under 35 U.S.C. § 102, because the proffered circumstance merely involves selecting a different stylet of a longer or shorter fixed length. The proffered circumstance does not encompass a single stylet of variable length. Additionally, there is no actual basis in Miller for the assertion that multiple stylets of different lengths are provided for

selection by the physician.

The rejection further asserts that ejector member 13 of Miller is coiled and, hence, is compressible. However, there is no basis in Miller to support the assertion that ejector member 13 is coiled. Miller only states that ejector member 13 could be formed of Teflon rod or a wire having an outside diameter about equal to the inside diameter of the cannula of Miller. Col. 2, lines 59-63.

Additionally, there is no disclosure that ejector member 13 is “compressible” to “maintain the tip in an alignment against the sharp cutting end to form a flush surface at the distal end of the bendable tubular needle.” Also, as previously noted, ejector member 13 merely possesses a “blunt” surface and does not fit “flush” against a sharp cutting end. Also, the stainless steel construction of stylet 12 of Miller is clearly not capable of being “compressed” in the manner recited by claim 29.

Furthermore, there is no disclosure that either stylet 12 or ejector member 13 are adapted to mate with a structure on the tubular needle so as to compress the variable length body of the removable stylet.

Therefore, claim 29 is not anticipated by Miller. Claims 30 and 31 depend from claim 29 and are likewise not anticipated by Miller.

F. CLAIM 4

Claim 4 depends from claim 1 and further recites ‘wherein the flexible stylet body further comprises a coil.’

Stylet 12 and ejector member 13 of Miller are not described as comprising a coil. Stylet 12 is described as including rod 20 of stainless steel. Ejector member 13 is only described as being formed of a rod or wire.

Accordingly, Miller does not disclose a flexible stylet body that comprises a coil and, hence, does not anticipate claim 4.

G. CLAIM 30

Claim 30 depends from claim 29 and further recites “wherein the flexible stylet body comprises a coil.”

Stylet 12 and ejector member 13 of Miller are not described as comprising a coil. Stylet 12 is described as including rod 20 of stainless steel. Ejector member 13 is only described as being formed of a rod or wire.

Accordingly, Miller does not disclose a flexible stylet body that comprises a coil and, hence, does not anticipate claim 30.

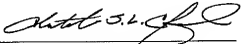
H. CONCLUSION

Appellant has demonstrated that the present invention as claimed is not anticipated by Miller. Therefore, Appellant respectfully requests the Board of Patent Appeals and Interferences to reverse the final rejection of the Examiner and instruct the Examiner to issue a notice of allowance of all claims.

Appellant has enclosed the appropriate fee to cover the cost of this APPEAL BRIEF. Appellant does not believe that any additional fees are due.

Respectfully submitted,

Date: 05-10-2006


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CLAIMS APPENDIX

1. (Previously Presented) A bendable needle system, comprising:
a bendable tubular needle having at least one sharp cutting end; and
a removable stylet inserted in a hollow interior of the bendable tubular needle, wherein the removable stylet further comprises:
a flexible stylet body that allows the stylet to bend within the bendable tubular needle;
and
a tip that aligns flush to the sharp cutting end of the bendable tubular needle;
wherein the bendable tubular needle is bendable by manual manipulation when the removable stylet is inserted in the bendable tubular needle and the removable stylet remains removable from the bendable tubular needle after the bendable tubular needle is bent.
2. (Original) The bendable needle system of claim 1, further comprising a fitting coupled to a non-cutting end of the hollow interior of the needle.
3. (Original) The bendable needle system of claim 2, wherein the fitting comprises a handle, and wherein an object may be inserted into the hollow interior of the bendable tubular needle via a passage within the fitting.
4. (Original) The bendable needle system of claim 1, wherein the flexible stylet body further comprises a coil.
5. (Original) The bendable needle system of claim 1, wherein the flexible stylet body further comprises a flexible rod.

6. (Original) The bendable needle system of claim 1, wherein the flexible stylet body further comprises a flexible tube.

7. (Withdrawn) The bendable needle system of claim 1, wherein a cross-section of the hollow interior comprises a shape in which a plurality of points along the shape's perimeter are not equidistant from a longitudinal axis of the bendable tubular needle.

8-21. (Cancelled)

22. (Withdrawn) The bendable needle system of claim 1, wherein said sharp cutting end is oval.

23. (Withdrawn) The bendable needle system of claim 7, wherein said cross-section of said hollow interior is oval in shape.

24-28. (Cancelled)

29. (Previously Presented) A bendable needle system, comprising:

a bendable tubular needle having a sharp cutting end at a distal end and a hollow fitting structure at a proximal end;

a removable stylet, of variable length, inserted in a hollow interior of the bendable tubular needle, wherein the removable stylet further comprises:

a fitting structure adapted to mate with the hollow fitting structure of the bendable tubular needle;

a flexible stylet body that allows the stylet to bend within the bendable tubular needle, wherein the flexible stylet body aids in maintaining patency of the bendable tubular needle when the bendable tubular needle is bent; and

a tip, wherein the fitting structure, when mated with the hollow fitting of the bendable tubular needle, compresses the flexible stylet body to maintain the tip in an alignment against the sharp cutting to form a flush surface at the distal end of the bendable tubular needle;

wherein the bendable tubular needle is bendable by manual manipulation when the removable stylet is inserted in the bendable tubular needle and the removable stylet remains removable from the bendable tubular needle after the bendable tubular needle is bent.

30. (Previously Presented) The bendable needle system of claim 29 wherein the flexible stylet body comprises a coil.

31. (Previously Presented) The bendable needle system of claim 29 wherein a cross-section of the hollow interior is oval in shape.

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EVIDENCE APPENDIX
(NOT APPLICABLE)

RELATED PROCEEDINGS APPENDIX

(NOT APPLICABLE)